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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,422	05/03/2006	Mats Ranby	RANB3002/REF	5307

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BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,422	RANBY, MATS	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/05, 11/15/06, 7/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "said" and "comprises". In addition, on line 7 of the abstract, the phrase "temperature recoding means" should be changed to --temperature recording means--. Correction is required. See MPEP § 608.01(b).

4. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In part b) of claim 1, the phrase "the reaction mixture" lacks antecedent basis. On line 8 of claim 1, the phrase "the steps a) and b) being performed in an optional order" is indefinite since the sample and the liquid reagent have to be mixed together first before the temperature of such a mixture can be determined. It is impossible for the temperature of a mixture of the sample and the liquid reagent to be measured first before the mixture is even formed. Therefore, step a) in the method of claim 1 must come before step b), and cannot optionally come after step b).

On line 2 of claim 10, the phrase "temperature recoding means" is indefinite and should be changed to --temperature recording means--.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Moyer et al (US Patent 3,951,606, submitted in the Information Disclosure Statement filed on December 14, 2005).

Moyer et al teach of a method and apparatus used for prothrombin testing on a blood sample. The apparatus comprises a uniform bore reaction tube or vessel containing therein liquid reagents for clotting a blood or plasma sample that have been lyophilized. The liquid reagents include thromboplastin and other additives for clotting blood. The tube contains calibration marks thereon that serve to indicate the volume of sample in the tube (i.e. the calibration marks serve as a volume determining means). To use the device to perform a prothrombin test, a sample of whole blood or plasma is obtained from a finger puncture, and the blood is added to the top of the tube. The sample of blood descends in the tube, thereby contacting the dried coagulation reagents. The sample continues to descend in the tube until the time at which a clot forms that serves to stop any further movement of the sample in the tube. Moyer et al teach that prothrombin times are normally obtained at a temperature of 37^0C. However, Moyer et al teach that using the reaction tube described, a prothrombin time test can be performed at room temperature provided a calibration plot is constructed which relates the two sets of data (i.e. the

standard prothrombin times obtained at 37^{0}C, and prothrombin times obtained at a room temperature of about 22-23^{0}C). Therefore, the method taught by Moyer et al includes the steps of mixing in a vessel a sample of blood with reagents that become liquid upon combination with a blood sample, determining the room temperature of the mixture in the range of about 22-23^{0}C, determining the clotting time of the sample that correlates to the distance of the downward travel of the sample in the vessel before coagulation, and calculating the prothrombin time of the blood sample based upon both the measured clotting time and the temperature of the sample. The prothrombin time of the sample is determined by using a calibration table of rows and columns where one of the rows and columns includes clotting times, and the other of the rows and columns includes temperatures such as 22^{0}C, 23^{0}C and 37^{0}C. The clotting time of the sample measured at an ambient temperature of 22-23^{0}C is compared to the clotting time of a sample measured at 37^{0}C using the same apparatus in order to determine the prothrombin time of the blood sample. Therefore, the prothrombin time of a blood sample is determined in the method and apparatus taught by Moyer et al using both a determination of the temperature and the clotting time of the sample. See Figures 1-2, the abstract, lines 33-51 in column 2, lines 35-60 in column 4, lines 1-15 and 41-62 in column 5, lines 25-51 in column 6 and the claims in Moyer et al.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 7, 10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moyer et al (US 3,951,606). For a teaching of Moyer et al, see previous paragraphs in this Office action.

Moyer et al fail to teach that the prothrombin time of a blood sample can be measured in the uniform bore tube at a temperature of 30-35^{0}C, in accordance with the recitation of instant claim 7. However, it would have been obvious to one of ordinary skill in the art to measure the prothrombin time of a blood sample at a temperature of 30-35^{0}C using the apparatus taught by Moyer et al since Moyer et al teach that the apparatus can be used at room temperature in order to measure the prothrombin time of a blood sample, and the temperature range of 30-35^{0}C falls into the category of "room temperature" in some circumstances.

Moyer et al also fail to teach that the apparatus for determining prothrombin time of a blood sample can be incorporated into a kit including a vessel having lyophilized coagulation reagents therein, a temperature recording means, a time registration means and a volume determining means. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the apparatus taught by Moyer et al including a vessel having lyophilized coagulation reagents therein and a volume determining means (i.e.

calibration marks) into a kit so as to provide a single use packaged device to a user in a ready-to-use form for the performance of a point-of-care prothrombin test that is quick and easy to use by having all of the required materials needed to perform the test in one location. It also would have been obvious to one of ordinary skill in the art to include a temperature recording means in the apparatus taught by Moyer et al since Moyer et al disclose the performance of the prothrombin test at a temperature other than the standard 37^0C, such as room temperatures of about 22-23^{0}C, and thus a temperature recording means would serve to measure the exact temperature at which the test is being performed. It also would have been obvious to one of ordinary skill in the art to incorporate a time registration means in the apparatus taught by Moyer et al so as to provide a simple measurement of the time it takes a blood sample added to the tube to coagulate without having to rely on the measurement of the distance traveled in the tube by the blood sample.

10. Claims 1-7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art on pages 1-2 of the instant specification in view of Zweig (WO 93/22453, submitted in the IDS filed on December 14, 2005).

Applicant admits on pages 1-2 of the instant specification that it is known in the prior art to perform a prothrombin time test on a blood sample at 37^0C by combining a blood sample with liquid thromboplastin reagents and determining the time needed for the mixture to clot. The prothrombin time is expressed as an International Normalized Ratio (INR). Applicant also admits that in an Owren-type PT test, it is known to include in the PT reagent a sufficient amount of fibrinogen to increase the fibrinogen content of the mixture of sample and reagent by at least 0.1 g/L, and that the relationship between reagent and sample in an Owren-type PT test is greater

than four. Applicant admits that known, prior art PT tests are commonly performed at 37^0C in order to mimic the physiological situation. However, this requires that some sort of thermostat/heating means be present in the device for measuring prothrombin time in order to maintain a temperature of 37^0C. See pages 1-2 of the instant specification. Applicant fails to teach that a prothrombin time test can be performed at an ambient room temperature of between 15-45^0C, and that the measured ambient temperature can be used in the measurement of the prothrombin time in order to compensate for the temperature at which the test was performed.

Zweig teaches of a test article and a method for performing a blood coagulation assay such as prothrombin time. Zweig teaches that the blood coagulation test can be performed at room temperatures thereby eliminating the need for elaborate temperature control means. The coagulation apparatus taught by Zweig comprises a control circuitry which includes a temperature measurement capability so that variations in temperature can be taken into account when interpreting the test results. The circuitry further includes calculating means for calculating the coagulation value of blood. Zweig teaches that if the prothrombin time test is performed at ambient temperature, the temperature of the sample and reagent is determined by a temperature recording means such as a thermocouple, and the PT time is adjusted accordingly. Therefore, the circuitry includes a temperature adjustment algorithm that compensates the measured prothrombin time for temperature. In other words, the initially determined coagulation value is adjusted upwards or downwards to compensate for variations in the sample temperature that is at ambient temperature different from the standard 37^0C. See lines 3-15 on page 6, lines 9-28 on page 16 and lines 1-26 on page 17 of Zweig.

Based upon the combination of Applicant's admitted prior art and Zweig, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to perform the prothrombin time test taught as known by Applicant on pages 1-2 of the instant specification at an ambient room temperature of between 15-45^{0}C, and to use the measured ambient temperature in the measurement of the prothrombin time since Applicant admits that it is cumbersome to perform the known prothrombin time test at 37^{0}C since this requires a thermostat/heating means, and Zweig teaches that prothrombin time tests can be performed at ambient temperatures lower than 37^{0}C by simply measuring the temperature of a sample/reagent mixture in the range of an ambient/room temperature, and incorporating this measurement into the calculation of the prothrombin time using some sort of temperature adjustment algorithm that serves to temperature compensate the PT coagulation value. It also would have been obvious to one of ordinary skill in the art to incorporate the components needed to perform the known prothrombin time test taught by Applicant in the specification, including a vessel containing liquid reagents for clotting a blood sample and a timing means for measuring the time required for a sample combined with the reagents to coagulate, into a kit form so as to provide a single use packaged device to a user in a ready-to-use form for the performance of a point-of-care prothrombin test that is quick and easy to use by having all of the required materials needed to perform the test in one location. It would have been obvious to one of ordinary skill in the art to include a temperature recording means in the kit of the prothrombin time test taught by Applicant for the purpose of measuring the ambient temperature of the sample being tested in accordance with the teaching of Zweig to perform prothrombin time tests at ambient temperatures and to temperature compensate the measured prothrombin values. It also would have been obvious to one of ordinary skill in the art

to include a volume determining means in the kit of the prothrombin time test taught by Applicant for the purpose of measuring the amount of blood tested and the amount of blood that coagulates during the test.

11. Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a method for determining prothrombin time of a blood sample by calculating the International Normalized Ratio (INR) of the sample using the equation set forth in claim 8.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Zweig (US Patents 5,580,744 and 5,418,143) and Jina (US Patent 6,046,051) who teach of test devices for determining blood coagulation parameters.

Applicant is informed that the two foreign patent documents in the Information Disclosure Statement (IDS) filed on November 16, 2006 have been crossed out by the Examiner since these same references were already considered and made of record in the IDS filed on December 14, 2005.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

June 25, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797